# MEETING MINUTES

## FDA & University of Michigan

## Pre-Submission Meeting [redacted]

## High density Interconnects with Variable Electronics (HIVE) Recording Module

## Monday, July 24, 2021

## 1:00 p.m. to 2:00 p.m. EST

Attendees on behalf of the FDA:

[redacted]

Attendees on behalf of the University of Michigan

- Paul Cederna, MD – IDE Sponsor/Investigator, Robert Oneal Collegiate Professor of Plastic Surgery, Professor Department of Biomedical Engineering
- Cynthia Chestek, PhD – Associate Professor, Department of Biomedical Engineering
- Alex Vaskov, PhD – Research Fellow, Department of Biomedical Engineering
- Mona Moore, MS – Lead Regulatory Project Manager, MICHR MIAP
- Misty Gravelin, MS – Regulatory Project Manager, MICHR MIAP
- Rivka Siden, PharmD – Regulatory Project Manager, MICHR MIAP

Attendees on behalf of Case Western Reserve University

Megan Moynahan - Executive Director, Institute for Functional Restoration, CWRU

The FDA started the meeting at 1:02 pm.

UM team asked for clarification in regards to Question 1 on the FDA written feedback. In particular the statement “The FDA recommends that you evaluate the generated heat at the active implant region via bench testing and provide this assessment in your future IDE Supplement. We also recommend that you include a plan for monitoring adverse events related to heating in your future protocol to ensure adverse events that may results from heating are adequately captured.” UM wanted more clarification on the method for monitoring the adverse events.

FDA replied that thermal injury is a real concern and wanted to make sure this risk was covered in the risk mitigation plan. Bench top testing to measure the temperature of the device can help mitigate the concern. Risk can also be measured by having a patient questionnaire and asking if they experienced any burns or discomfort.

UM's second question regarded the FDA comment in Question 2 of the written feedback that for the noted early feasibility study, they agree that if the recording module is non-functional due to an ESD event, replacing the recording module is an appropriate mitigation for ESD. UM wanted clarification if this would be true for an implanted version of the recording module.

The FDA clarified that for an implantable device there is a concern about a surgical intervention being required in order to remove the device (you can't just take if off). For fully implantable devices, there needs to be some scrutiny of each device to determine that it is working before it is implanted in a larger number of people. FDA recommended a q-sub submission and meeting before moving on to the implantable device as there will be other items to consider such as the risk profile, device test and requirements for the implantable device.

The last point of clarification for UM was in regards to how to format a hazard analysis for a system that has many modular pieces. UM asked if the hazard analysis should be broken down into sections such as power module, HIVE module and system as a whole. FDA confirmed that doing a hazards analysis for each individual device as well as a hazard analysis for the whole system would be suitable.

UM and CWRU indicated that this project was part of a larger project and wanted to alert the FDA that a pre-submission for the larger project would be submitted later this year. The study team would like to eventually have a master file that other teams would be given a right of reference to use and would like to have FDA feedback on items such as a risk assessment table template that other teams could use. FDA confirmed that having something standard for other teams to use would be helpful and they are willing to help in any way they can. The study team should feel free to email or call the FDA if they have simple questions that would not necessarily require a pre-submission meeting.

The meeting was adjourned at 1:19 pm.